K091763 1/2

510(k) Summary

Submitter:

Instratek, Inc.
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AUG 14 2009

Contact person:

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Vice President

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Date summary prepared: June 12, 2009

Device trade name: Michelangelo Bunion System

Device common name: Button/Suture

Device classification name: Washer,Bolt Nut, HTN at 21 CFR 888.3030

Legally marketed devices to which the device is substantially equivalent:

HAV-Lok Bunion Correction System, K082384
Arthrex Mini-Tightrope, K061925

Description of the device:

The Instratek Michelangelo Bunion System is intended to assist in the correction of Hallux Valgus deformities by providing reduction of the 1st. intermetatarsal angle.
Like the predicate device, the Michelangelo Bunion System is intended to assist in the correction of hallux valgus deformities by providing reduction of 1st intermetatarsal angles up to and including 16 degrees. The Michelangelo Bunion System may eliminate the necessity of a traditional osteotomy in the correction of Hallux Valgus deformities within the indicated criteria. The implanted device consists of three components

1. Medial Plate
2. Lateral Plate
3. Suture

There are 6 accessories required to implant the device

1. suture lasso
2. kwire
3. cannulated drill bit
4. kwire guide
5. plate bender
6. suture scissor

Intended use of the device:	The Michelangelo Bunion System is intended for the following surgical indication: • To assist in the correction of hallux valgus deformities by providing reduction of the 1st intermetatarsal angle.
Technological characteristics:	The technological characteristics between the predicate and proposed devices are the same.
Performance tests:	Performance tests included knot pull testing which was performed with the predicate device submission.
Conclusions:	There are no significant differences between the proposed and predicate device; therefore, the proposed device does not raise any questions regarding safety and effectiveness. The Michelangelo Bunion System, as designed, is as safe and effective as the predicate devices. Comparisons have been made to a legally marketed predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Instratek, Inc.
% Mr. Jeff Seavey
210 Springhill Drive, Suite 130
Spring, Texas 77386

AUG 1 4 2009

Re: K091763
Trade/Device Name: Michelangelo Bunion System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HTN
Dated: July 15, 2009
Received: July 23, 2009

Dear Mr. Seavey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K091763

Device Name: Michelangelo Bunion System

Indications for Use: The Michelangelo Bunion System is intended for the following surgical indication:

- To assist in the correction of hallux valgus deformities by providing reduction of the 1st intermetatarsal angle.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091763